UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte LEWIS T. WILLIAMS, JAMIE ESCOBEDO, MICHAEL A. INNIS, PABLO DOMINGUEZ GARCIA, JULIE SUDDUTH-KLINGER, CHRISTOPH REINHARD, KLAUE GIESE, FILIPPO RANDAZZO, GIULIA C. KENNEDY, DAVID POT, ALTAF KASSAM, GEORGE LAMSON, RADOJE DRMANAC, RADOMIR CRKVENJAKOV, MARK DICKSON, SNEZANA DRMANAC, IVAN LABAT, DENA LESHKOWITZ, DAVID KITA, VERONICA GARCIA, LEE WILLIAMS JONES, BIRGIT STACHE-CRAIN

Appeal No. 2004-1932
Application No. 09/297,648

ON BRIEF

Before SCHEINER, ADAMS, and GREEN, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 146-154, which are all the claims pending in the application.

Claim 146 is illustrative of the subject matter on appeal and is reproduced below:

1. An isolated polynucleotide comprising at least 50 contiguous nucleotides of a sequence selected from SEQ ID NO: 253 and the complement thereof.

The examiner does not rely on a reference.

GROUND OF REJECTION

Claims 146-154 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description.

We reverse.

CLAIMS CONSTRUCTION

As we understand the claimed invention, the claims are drawn to an isolated polynucleotide of at least 50 contiguous nucleotides from SEQ ID NO:253[1] which may be flanked on either side by any number of nucleotides, of any sequence, a vector that contains this polynucleotide and a host cell that contains the claimed vector. While the claimed polynucleotide may be flanked on either side by any number of nucleotides, or any sequence, we interpret the claimed invention to exclude any internal alterations (e.g. insertions or deletions) of the 50 contiguous nucleotides from SEQ ID NO:253.

DISCUSSION

Initially, we note that the examiner finds, "SEQ ID NO:253 meets the written description provision[ ] of 35 USC [§] 112, first paragraph." Answer, bridging sentence, pages 3-4. Nevertheless, as we understand the examiner's rejection, because the claims use the transitional phrase "comprising", the claims encompass a large genus of nucleic acid molecules which are not adequately described by SEQ ID NO:253. See e.g., Answer, bridging sentence, pages 5-6,

[1] In the alternative the claim provides that the 50 contiguous nucleotides can be from the complementary strand of a nucleic acid molecule having SEQ ID NO:253, or as set forth in claim 151 from "an insert contained in a vector deposited as clone number M00001448D:C9 of A.T.C.C. Deposit Number 207068...."

"[i]t is the open language applied to SEQ ID NO:253 that causes the rejection for lack of written description." See also, Answer, page 4:

> [C]laims 146-154 encompass full length cDNA comprising SEQ ID NO:253, genomic sequences that hybridize to SEQ ID NOL253, and vectors and host cells comprising full length cDNA comprising SEQ ID NO:253. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

According to the examiner (Answer, page 5), "the claims read on a multitude of undescribed fragments of full length cDNA that are larger than SEQ ID NO:253. The number of undescribed species cannot be determined because the length of the corresponding full length cDNA is unknown."

We have interpreted the claims to allow for the addition of nucleotides at either end of the recited nucleotide sequences, but not to allow for internal alterations (e.g. insertions or deletions) of the nucleotide sequence of the claimed polynucleotide. Accordingly, we agree with Appellants that the claims, as we have interpreted them, are supported by an adequate written description in the specification. The fact that the claimed polynucleotide may have other nucleotides attached to either or both of its 5' or 3' end does not diminish Appellants' adequate written description of the polynucleotide as set forth in the claimed invention.

We do not agree with the examiner that the lack of a structural description for the full-length cDNAs, genomic sequences, vectors, or etc. as they are encompassed by the claimed polynucleotide means that the claims are inadequately described. The first paragraph of 35 U.S.C. § 112 does not require

a description of the complete structure of every species within a chemical genus. See Utter v. Hiraga, 845 F.2d 993, 998, 6 USPQ2d 1709, 1714 (Fed. Cir. 1988) ("A specification may, within the meaning of 35 U.S.C. § 112, ¶ 1, contain a written description of a broadly claimed invention without describing all species that claim encompasses.").

This standard applies to DNA as well. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 139, 1406 (Fed. Cir. 1997). Further, post-Lilly, the court has clarified that the representative species need not necessarily be described in terms of their complete chemical structure. See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 1324, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002) ("[T]he written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.'" (emphasis omitted, alterations in original)).

In addition, our appellate reviewing court has also noted that "Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement

may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure." Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1332, 65 USPQ2d 1385, 1398 (Fed. Cir. 2003).

Thus, the lack of a structural description of full-length, protein-encoding DNA sequences that encompasses SEQ ID NO: 253 is not, in itself, enough to support a rejection for lack of written description. The examiner bears the initial burden of showing that a claimed invention is unpatentable. See In re Alton, 76 F.3d 1168, 1175, 37 USPQ2d 1578, 1583 (Fed. Cir. 1996). That burden has not been carried here. Accordingly, we reverse the rejection of claims 146-154 under 35 U.S.C. § 112, first paragraph, as lacking an adequate written description.

REVERSED

Toni R. Scheiner)
Administrative Patent Judge)
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) BOARD OF PATENT
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Donald E. Adams) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
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Lora M. Green)
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